

# QMS GAP ASSESSMENT

Providing your team with actionable insights to streamline activities and improve operations and performance.





### What We Do



We leverage advanced analytics to help Quality leaders identify compliance risks and areas of opportunity for improvement.

- > Strong framework and advanced tools
- > High value, low cost
- Highly experienced industry professionals

High Level Review & Assessment	Deep Dive Review & Assessment				
2 to 6 weeks	1 to 3 months				
1 to 4 consultants	2 to 20 consultants				
~\$15k per QS element	~\$50k per QS element				

We conduct analyses for each Quality System (QS) element, we look at multiple regulatory and operational dimensions, well beyond the review of your SOPs vs cGMPs.

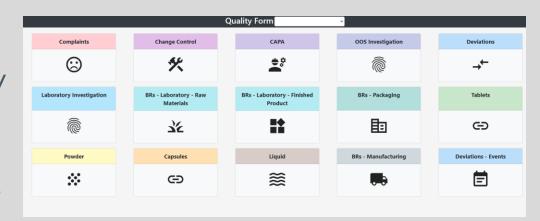
- Quality System Elements: Batch Records, Deviations, CAPA, Complaints, Change Control, etc.
- Dimensions: QA Oversight, RCA, Risk Assessment, Effectiveness Check, cGMP, SOP adherence, GDP, etc.

### How We Do It



- 1. Deploy proprietary templates and checklists
- Highly experienced consultants review QualitySystem element documents
- 3. Apply advanced analytics to generate insights on outcome of reviews





ecord #	Reviewer	Status	Date Review Started	Date Completed	Location	Quality System	Record Type	Product Configuration	Year ▼	Review Type	Product Name	Outcome	Lots Impacted	Client Risk Classific						
307					On-Site	Batch Records	Manufacturing	Powder	2020	Prospective										
770		Closed	06/11/2020	06/12/2020	On-Site	Batch Records	Manufacturing		2020	Prospective		Did Not	None							
315A			06/10/2020	06/10/2020		Batch Records	Packaging		2019	Retrospective		Action Re								
83			06/08/2020	06/08/2020		Batch Records	Manufacturing	Capsules	2019	Retrospective										
115			06/10/2020	06/10/2020		<b>Batch Records</b>	Manufacturing	Liquid	2019	Retrospective										
83A			06/09/2020	06/09/2020	Remote	Batch Records	Packaging		2019	Retrospective	. Ac	Action Re								
PA-2019-0027			05/13/2020	05/13/2020	Remote	CAPA			2019	Retrospective		Did Not								
PA-2019-0026			05/13/2020	05/13/2020	Remote	CAPA			2019	Retrospective		Did Not	14886							
V-2019-0339			05/20/2020	05/20/2020	Remote	Deviations			2019	Retrospective		Met GMP	15895	Major						
V-2019-0361			05/19/2020	05/19/2020	Remote	Deviations			2019	Retrospective		Did Not	15934	Major						
/-2019-0381			05/08/2020	05/09/2020	Remote	Deviations			2019	Retrospective		Did Not	15925A	Major						
PA-2019-0025			05/13/2020	05/13/2020	Remote	CAPA			2019	Retrospective		Did Not	14390A							
PA-2019-0024			05/13/2020	05/13/2020	Remote	CAPA			2019	Retrospective		Met GMP	Not documented in CA							
19-030		Closed	07/02/2020	07/02/2020	Remote	Complaints			2019	Retrospective		Met GMP	Not reported	Not Required By SOP						
PA-2019-0018			05/12/2020	05/12/2020	Remote	CAPA			2019	Retrospective										
PA-2019-0017			04/24/2020	05/12/2020	Remote	CAPA			2019	Retrospective			N/A							
PA-2019-0001			05/08/2020	05/08/2020	Remote	CAPA			2019	Retrospective			15079A							
19-029				Closed	07/02/2020	07/02/2020	Remote	Complaints			2019	Retrospective		Met GMP		Not Required By SOP				
968									Closed	06/17/2020	06/18/2020	Remote	Batch Records	Packaging		2018	Retrospective		Did Not	
168			Closed	06/18/2020	06/18/2020		Batch Records	Manufacturing	Tablets	2018	Retrospective		Did Not							
965		Closed	06/19/2020	06/19/2020	Remote	Batch Records	Manufacturing	Tablets	2018	Retrospective		Did Not								
948		Closed	06/23/2020	06/23/2020		Batch Records	Packaging		2018	Retrospective		Did Not								
948					Closed	06/22/2020	06/22/2020	Remote	<b>Batch Records</b>	Manufacturing	Tablets	2018	Retrospective		Did Not					
947		Closed	06/24/2020	06/24/2020	Remote	Batch Records	Packaging		2018 Retrospective	LILLANDO LACIDA LINA LINABALA	Did Not									

### Case Study



#### Situation:

A pharmaceutical company received a Warning Letter, OQSIE performed a gap assessment on the Quality System elements cited on the Warning Letter and developed a comprehensive remediation plan.

#### Approach:

Team of 20 consultants performed a deep dive assessment of all quality system elements leveraging our proprietary templates and checklists.

#### Outcome:

OQSIE identified and prioritized the areas of regulatory risk and opportunity for improvement for each QS element, and created a comprehensive remediation plan with the following major initiatives:

- > SOP redesign for Quality System elements identified in the Warning Letter
- Remediation of Quality Systems not cited in the Warning Letter
- > Interim Controls
  - Additional controls on QS currently in-scope (prospective reviews)
  - Controls on QS not currently in-scope (prospective reviews)
- > Other pro-active initiatives
  - > ANDA vs MBR Remediation
  - > Batch Record harmonization and simplification
  - Reconfiguration of MasterControl

## Case Study

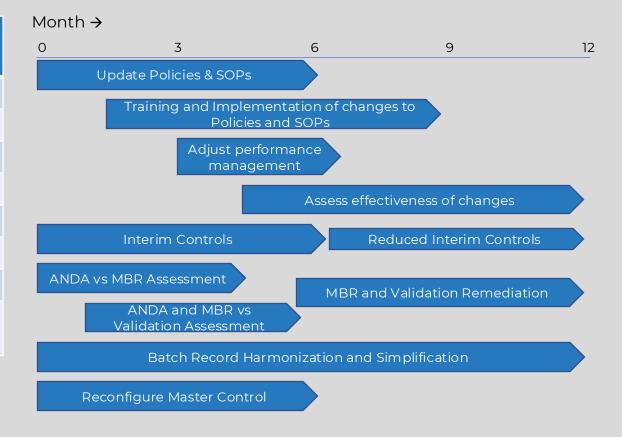


#### **Example of content of the Gap Assessment:**

#### Summary of Findings

Quality Systems Assessed	Synthesis of assessments
Complaints	High risk of additional regulatory action
Change Control	High risk of additional regulatory action
CAPA	High risk of additional regulatory action
Deviation Management	High risk of additional regulatory action
Validation	High risk of additional regulatory action
Laboratory Controls	Risk of additional regulatory action
Batch Release	Needs significant improvement
Training	Needs a different structure and approach

#### High Level Timeline of Remediation Plan



# Case Study



#### **Examples of Gap Assessment reports:**

		Key Activities
	Define Strategy for Policies & SOPs	Develop proposed strategy for Policies and SOPs     Syndicate proposed strategy with management team     Develop detailed plan to update relevant documents
2	Update Policy & SOP documents	<ul> <li>Update policy documents</li> <li>Update SOP documents</li> <li>Implement governance process to accelerate approval process</li> <li>Define KPI(s) for effectiveness check</li> </ul>
3	Process Change Control and Develop Training Materials	<ul> <li>Change Control submission</li> <li>In parallel, develop training materials for new and updated documents</li> <li>Develop training plan</li> <li>Define implementation plan and execute</li> </ul>
4	Training and Implementation	° Deliver training ° Execute implementation plan
5	Assess Change Effectiveness	° Conduct effectiveness check(s) ° If necessary, develop additional remediation plan

Common Areas impacting Quality Systems +	Compla ints §211.198	Investiga tions §211.192	QC Recor ds §211.19 4	BR Revie ws §211.18 8	Change Controls §211.100	CAPAs §211.192	QC Lab Inv. §211.194
GMP Compliance	Deficie nt	Deficient	Defici ent	Defici ent	Deficien t	Deficie nt	Deficie nt
Process / SOP	Deficie nt	Deficient	Defici ent	Defici ent	Deficien t	Deficie nt	Deficie nt
Training	Insuffic ient	Insufficie nt	Insuffi cient	Insuffi cient	Good	Good	Insuffic ient
Performance (SOP not followed)	Insuffic ient	Insufficie nt <sup>2</sup>	Good	Good	Good	Good	Insuffic ient
Deviations	Good	Insufficie nt	Insuffi cient	Insuffi cient	Insuffici ent	Insuffic ient	Good
Investigations (RCA and RA) <sup>1</sup>	Insuffic ient	Insufficie nt	Insuffi cient	Insuffi cient	Good	Good	Insuffic ient
САРА	Good	Insufficie nt	Good	Good	Good	Good	Insuffic ient
Systemic Challenges	Deficie nt	Deficient	Defici ent	Defici ent	Deficien t	Deficie nt	Deficie nt
GDP	Good	Insufficie nt	Insuffi cient	Insuffi cient	Good	Insuffic ient	Good
Equipment	Good	Good	Insuffi cient	Good	Good	Good	Good
Data Integrity	Good	Good	Insuffi cient	Insuffi cient	Good	Good	Good
EQMS <sup>3</sup>	Good	Good	Good	Good	Good	Insuffic ient	Good
Records	Deficie nt	Deficient	Defici ent	Defici ent	Deficien t	Deficie nt	Deficie nt
Validation	Good	Good	Insuffi cient	Insuffi cient	Insuffici ent	Insuffic ient	Insuffic ient
Adverse Event Complaints	Insuffic ient Third Party Contra ctor	Good	Good	Good	Good	Good	Good

We deliver detailed reports for each Quality System element.

Common Areas impacting Quality Systems ↓	Compla ints	Investigat ions	QC Records	BR Reviews	Change Controls	CAPA s	QC Lab Inv.
GMP Compliance	Deficie nt	Deficient	Deficien t	Deficien t	Deficient	Defici ent	Deficie nt
Records	Deficie nt	Deficient	Deficien t	Deficien t	Deficient	Defici ent	Deficie nt
Process / SOP	Deficie nt	Deficient	Deficien t	Deficien t	Deficient	Defici ent	Deficie nt
Investigations (RCA and RA) <sup>1</sup>	Insuffici ent	Insufficie nt	Insuffici ent	Insuffici ent	Good	Good	Insuffici ent
Systemic Challenges	Deficie nt	Deficient	Deficien t	Deficien t	Deficient	Defici ent	Deficie nt

Process	Assessment	Warning Letter?	SOP In Place	SOP in Compliance
Written procedures describing the handling of all written and oral complaints.	Does not meet criteria		Yes	No
QA Unit review of drug products that failed to meet specifications.	Complies			
For drug products that potentially failed to meet specifications, an investigation is conducted.	Does not meet criteria			
Process to identify serious and unexpected adverse drug experience (ADE).	Does not meet criteria			
Process to report the food and drug administration any ADE.	Does not meet criteria			
Written records for each complaint.	Does not meet criteria			
Files of each written complaint must be readily available for inspection.				
Written records must be maintained for specific time, per expiration date or complaint date, whichever is longer.				
Written records include (where known), Name and strength of the drug product. Lot number, name of complainant, and reply to complainant.				
Investigations include the findings and follow up.	Does not meet criteria			
Written record of investigations related to complaints are readily available.				
If an investigation is not conducted, a documented reason as to why the investigation was not conducted and the name of the person making such determination.	Does not meet criteria			



### Work With Us



We offer the **best value** for our client's money in the industry.

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